

## **REMARKS**

Claims 1-8, 12-20, and 26-38 are now pending in this application, and claims 9-11 and 21-25 have been cancelled without prejudice. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

## **SPECIFICATION**

The specification stands objected to for certain informalities. The Applicants have amended the specification according to the Examiner's suggestions. Therefore, reconsideration and withdrawal of this objection are respectfully requested.

## **DOUBLE PATENTING REJECTION OF CLAIMS 9-11 AND 19-31**

### **Claims 19, 20 and 26-31**

Claim 19 recites a method of mapping the electrical characteristics of the left atrium of the heart that includes the steps of moving the electrode into contact with the surface of the left atrium and measuring the electrical characteristics of the left atrium. This is different in scope from claim 9 of patent 6,385,472, which recites a method of ablating tissue that includes the step of applying an RF signal to the tissue in contact with the electrode to ablate the tissue. Thus, claim 19 is not coextensive in scope with the claims of U.S. Patent No. 6,385,472, and should not be subject to the statutory type double patenting rejection. As such, the Applicant believes that claims 19-20, and 26-31 are allowable for at least these reasons.

### **Claims 9-11, and 20-25**

Claims 9-11 and 20-25 have been cancelled without prejudice.

## **DOUBLE PATENTING REJECTION OF CLAIMS 1-8 AND 12-18**

The Applicant has filed a terminal disclaimer in accordance with 37 CFR 1.321(c) to overcome the above double patenting rejection. As such, the Applicant believes that claims 1-8 and 12-18 are allowable for at least these reasons.

### **REJECTION UNDER 35 U.S.C. § 102**

Claims 1-8 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Bourne et al (U.S. Pat. No. 5,911,720). This rejection is respectfully traversed.

#### **Claim 1**

At the outset, the Applicants submit that the amendments to claim 1 have rendered the above rejection moot. Claim 1 has been amended to clarify that the distal end portion of the extension member containing the at least one magnet is relatively rigid and the portion of the extension member just proximal to the at least one magnet is flexible, such that the catheter bends at a point proximal to the at least one magnet. The distal end portion of the catheter having the at least one magnet is relatively rigid. (See paragraph 28 of the present published application 200401581420). This is distinguished from Bourne et al., which discloses a non-rigid distal tip portion having three spring portions that allow three magnets to bend and reconfigure the shape of the distal tip portion. This is also distinguished from Hall et al., which discloses a distal end having an elongate magnetic element that bends when an external magnetic field is applied. Here, the distal end portion is rigid and the catheter bends at a point proximal to the distal end portion having the at least one magnet. (See paragraph 29 of the present published application 200401581420). Thus, the Applicants submit that claim 1 is distinguished from Bourne et al. As such, the Applicants believe claim 1, and claims 2-8 which depend from claim 1, are allowable for at least these reasons.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 12-18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall et al. (U.S. Pat. No. 6,292,678) in view of Fleischman et al. (U.S. Pat. No. 5,545,193). This rejection is respectfully traversed.

#### **Claim 12**

The Office Action states that Hall discloses a tubular magnetic member (36) that defines a passage in view of its tubular shape, which would provide a passage as recited in claim 12. However, claim 12 as presently amended clarifies that the electrode catheter has a lumen extending from the proximal end outside of a subject's body to the distal end, for enabling the introduction and delivery of fluids therethrough. Unlike conventional electrode catheters, the novel electrode catheter disclosed in the present application has an electrode and at least one magnetically responsive element for orienting the electrode to establish contact, while also permitting fluid flow through the magnetically responsive element and electrode to the distal end.

Upon review of Hall, the elongate magnetic tubular members (36, 56) are short segments that preferably conform to the shape of a wall W, and may include injectors or openings for delivering substances to the heart tissue. (Col. 6, ll 21-37). However, the catheters (30, 50) with magnetic tubular members (36,56) do not have lumens extending through to the proximal end, for enabling the introduction and delivery of fluids from a point outside of a subject's body. Rather, the catheters (30, 50) extend through a sheath 80 by means of a tether, which does not deliver fluids. (see Figures 2A-C, 3A-C). Hall states that once the sheath 80 is at the surgical site, a stylet can be inserted into the sheath to push the catheter from the sheath. (Col. 8, ll 27-34). Hall further states that the catheters (30, 50) can be provided with a lumen 90 as in Figure 7.

Contrary to the catheter of claim 12, the alternate catheter embodiments in Hall that include lumens (see Figures 7-13) have magnets (36, 102, 106) within the lumens, and do not have passages through the magnets. Accordingly, Hall teaches both a tethered catheter without a lumen extending through to the proximal end, or a catheter including a lumen that does not have a passage through at least one magnet. Thus, Hall neither teaches nor suggests a magnetically guided electrode catheter having a passage through a magnet and electrode for delivery of fluids from outside a subject.

There is also no motivation in Hall to modify a magnetically guided electrode catheter to include such a passage. The MPEP plainly states:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP § 2143).

Assuming that Hall's tethered catheters (30, 50 - with openings for delivering substances from within the tethered segment) works for its intended purpose, there would be no need, incentive, or motivation to further modify the catheters disclosed in Hall. There would be no reasonable expectation of success in modifying Hall, since providing a passage through the magnets (36, 102) in the "lumen" catheters shown in Figures 7 or 8 would reduce the magnet's size and hinder alignment with a magnetic field. Moreover, neither Hall or Fleischman teach or suggest all the claim limitations of a lumen extending from the proximal end outside of a subject's body to the distal end, for delivery of fluids therethrough, a first electrode at the distal end of the electrode catheter having at least one passage therethrough for delivery of fluids to the distal end of the

catheter, and at least one magnet at the distal end portion of the catheter having a passage therethrough for delivery of fluids to the distal end of the electrode catheter. With regard to Fleischman, this patent teaches various electrode strips as shown in Figures 42 and 45, but does not teach or suggest modifying a magnetically guided electrode catheter to include a passage through both a magnetically responsive element and an electrode for delivering fluids from the proximal through the distal end. Thus, the Applicants submit that claim 12 is distinguished from Hall and Fleischman. As such, the Applicants believe that claim 12, and claims 13-18 that ultimately depend from claim 12, are allowable for at least these reasons.

#### **NEW CLAIMS**

The Applicants have added new claims 35 -38, to claim additional features disclosed in paragraphs 28, 29 and 30 of the present published application 200401581420. The Applicants submit that no new matter has been added in these claims, which the Applicants believe to be allowable by virtue of the additional features that further distinguish these claims over Hall. Therefore, these claims should also be in a condition for allowance.

#### **CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and

favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314) 726-7505.

Respectfully submitted,

Dated: 9-5-06

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